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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/718,982 | 11/20/2003 | Ron L. Hale | 00067.01R | 2735 |

7590 03/08/2005

| EXAMINER |
|---|
| HAGHIGHATIAN, MINA |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

IP Department
Alexza MDC
1001 East Meadow Circle
Palo Alto, CA 94303

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/718,982 | HALE ET AL. | |
| | Examiner | Art Unit | |
| | Mina Haghighatian | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 25, 28, 43-44, 48, 59-60, 62-63 and 74-79 rejected under 35 U.S.C. 102(e) as being anticipated by Byron et al (20040016427 A1).

Byron et al disclose a method and apparatus for generating an aerosol. The aerosol is formed by supplying a material in liquid form to a tube and heating the tube such that the material volatizes and expands out of an open end of the tube. The volatized material combines with ambient air such that volatized material condenses to form the aerosol (see abstract and [0012]). The aerosols intended for inhalation typically have a mass median particle diameter of less than 2 microns (see [0074]). An example of a drug particle is budesonide ([0080]).

Byron et al disclose that the apparatus may be fairly large or may be miniaturized to be hand held (see [0086]).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byron et al (20040016427 A1) in view of Bartus et al (6,514,482).

Byron, discussed above, lacks specific disclosure on medicaments.

Bartus teaches a method of pulmonary delivery of a medicament, which includes administering to the pulmonary system and in particular to the alveoli or the deep lung particles comprising an effective amount of a medicament, where the particles preferably have an aerodynamic diameter between about 1 and about 5 μm. Particles can consist of the medicament or can further include one or more additional components. Rapid release of the medicament into blood stream and its delivery to its site of action (col. 3, lines 41-59).

Bartus discloses that medicaments which can be used in the said method include anti-inflammatory agents, anti-migraine agents, muscle relaxants, apomorphine, acetaminophen, lidocaine, diazepam, pindolol, diclofenac, valproic aid, flufenamic acid, isometheptene mucate, propoxyphene napsylate, luxapine succinate, etc (col. 5, line 35 to col. 7 line 20).

In a preferred embodiment, Bartus discloses that particles are delivered from an inhalation device, preferably they are administered via a dry powder inhaler (DPI),

metered dose inhaler (MDI), nebulizers or instillation techniques. Various suitable devices and methods of inhalation which can be used are known in the art (col. 7, line 24 to col. 8, line 8).

Bartus discloses that at least 50% of the mass of the particles stored in the inhaler receptacle is delivered to a subject's respiratory system in a single breath activated step. Amounts of drug or medicament present in the particles can range from 1 to about 90 weight percent (col. 8, lines 26-41). Bartus lacks teachings on producing condensation aerosol and also lacks specific disclosure on the presence of less than 5% degradation products.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the medicaments of Barus et al in the aerosol device article of Byron et al for delivering the aerosolized compositions to a subject's respiratory tract because it would be desirable to provide a wide variety of therapeutic agents in an aerosol delivery article which is capable of producing condensate aerosol particles of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or high temperatures. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.

Claims 20-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al (6,041,777) in view of Bartus et al (6,514,482).

Faithfull teaches methods and apparatus for closed-circuit ventilation therapy. In procedures involving liquid ventilation, this treatment and recirculation of the exhaled gases, vapors or liquids substantially reduces the amount of respiratory promoter needed to provide effective ventilation (col. 10, lines 13-26). Faithfull discloses that the nebulizer is used to provide fluorochemicals, heated above body temperature, to the ventilating gas in the form of a vapor. This may be accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. The fluorochemical liquid medium is particularly well dispersed in the lungs. As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces (col. 16, lines 44-67).

Faithfull also discloses that the said method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors (col. 25, lines 15-30). Faithfull lacks disclosure on medicaments.

Bartus et al, discussed above, discloses a wide variety of therapeutic agents suitable for aerosol delivery.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the method and apparatus for ventilation therapy as taught by Faithfull by adding the wide variety of medicaments suitable for aerosol delivery as taught by Bartus, because of the disclosed benefits of such a method,

including minimized trauma to the lungs and a better resolution of pulmonary and systemic disorders, and because of the need to treat a wide variety of diseases. Furthermore one of ordinary skill in the art would know that condensates have a high percentage of purity of the drug and less degradation products. Also noted that optimization of concentration ranges will not support patentability. Additionally, kits, including instructions are obvious and known to one of ordinary skill in the art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,716,415; 6,716,416; 6,716,417; 6,737,042; 6,737,043; 6,740,307; 6,740,308; 6,740,309; 6,743,415; 6,759,029; 6,776,978; 6,780,399; 6,780,400; 6,783,753; 6,797,259; 6,803,031; 6,805,853; 6,805,854; 6,814,955 and 6,855,310.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-82 are generic to all that is recited in claims of cited U.S. Patents. That is, claims of cited U.S. Patents fall entirely within the scope of claims 1-82, or in other words, claims 1-82 are anticipated by claims of cited U.S. Patents. Specifically, the compositions for delivery and the kits comprising the compositions and devices for their delivery of the instant claims are the same as compositions and kits of the cited U.S. Patents. The instant claims recite all the therapeutic agents included in the cited Patents. Due to the excessive number of claims in the instant application and the excessive number of related Patents, the claims have to be grouped and the examination has to be general.

Claims 1-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos (publication document Nos), 20030138382; 20030206869; 20040009128; 20040096402; 20040099266; 20040099269; 20040101481; 20040105818; 20040105819; 20040126326; 20040126327; 20040126328; 20040126329; 20040127481; 20040127490; 20040156788; 20040156789; 20040156790; 20040156791; 20040161385; 20040167228; 20040170569; 20040170570; 20040170571; 20040170572; 20040170573; 20040171609; 20040184996; 20040184997; 20040184998; 20040184999; 20040185000; 20040185001; 20040185002; 20040185003; 20040185004; 20040185005;

20040185006; 20040185007; 20040185008; 20040186130; 20040191179; 20040191180; 20040191181; 20040191182; 20040191183; 20040191184; 20040191185; 20040202617 and 20040228807. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 1-82 are generic to all that is recited in claims of cited copending Application Nos (publication document Nos). That is, claims of cited copending Application Nos (publication document Nos) fall entirely within the scope of claims 1-82, or in other words, claims 1-82 are anticipated by claims of cited copending Application Nos (publication document Nos). Specifically, the compositions for delivery and the kits comprising the compositions and devices for their delivery of the instant claims are the same as compositions and kits of the cited copending Application Nos (publication document Nos). The instant claims recite all the therapeutic agents included in the cited copending Application Nos (publication document Nos). Due to the excessive number of claims in the instant application and the excessive number of related copending Application Nos (publication document Nos), the claims have to be grouped and the examination has to be general.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
March 01, 2005

MICHAEL HARTLEY
PRIMARY EXAMINER